SEP 2 8 2000

# 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

**1) Submitter's name, address telephone number, contact person:**

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Phone: (425) 487-7000

Date Prepared:

**2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

| | |
|---|---|
| Common /Usual Name: | Picture Archiving and Communications System (PACS) Workstation |
| Proprietary Name: | MedLink, Diagnostic Offline Workstation |
| Classification Name: | Picture archiving and communications system<br>Class II (special controls; voluntary standards - Digital)<br>21 CFR 892.2050 |

**3) Device Description:**

Picture archiving and communication systems (PACS) are computer-based image storage and retrieval systems that can store and recall images in digital format from several different imaging modalities. The MedLink Workstation is an image management system that provides the capability for the acquisition, display, storage, and retrieval of medical images and patient data at a single or multiple locations for ultrasound. It also provides the user with the ability to import and view images from other modalities (CR, CT, MR, Nuclear Medicine, X-ray Angiography). By incorporating the Digital Image Communication in Medicine (DICOM) standard for medical network protocol transfers, the interface among the various system components and exchange of information is facilitated, providing compatibility with diagnostic imaging systems, printers, archival and review stations from many manufacturers.

**4) Performance Standards:**

No performance standards for PACS systems or components have been issued under the authority of Section 514. The MedLink Workstation Network has, however, been

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designed to comply with the following voluntary standards: ACR/NEMA Digital Image Communication in Medicine (DICOM) For Medical Network Protocol Transfers; ISO Joint Photographic Experts Group (JPEG) Image Compression Standard; Data Exchange File Format (DEFF) Advanced Technology Laboratories defacto Standard for Disc Based Image Transfers; IEEE 802 Local Area Network (LAN) Specification for Ethernet Network Configurations; Underwriter Laboratories (UL) Standard No. 1950, Tagged Image File Format (TIFF) defacto standard for Image Transfers, and Electronic Industries Association Standards Nos. RS-170 and RS-343, Electrical Performance Standards, Monochrome Television Studio Facilities.

**5) General Safety and Effectiveness Concerns:**

The device labeling contains operating instructions for the safe and effective use of the MedLink Workstation. The acquisition, display, storage and retrieval of information provides a minor level of hazard concern, based on an assessment of minimal patient risk related to the use of a PACS network for the storage and recall of patient information and anatomical images.

**6) Substantially Equivalent Devices:**

ATL believes that the image management technology, network capabilities and DICOM standard compatibility makes the MedLink Workstation substantially equivalent to other products currently in commercial distribution, specifically the ALI UltraPACS Image Management System and the Kodak Access Image Management System.

**7) Software:**

Software development for the MedLink Workstation follows documented processes for software design, verification and validation testing. A risk analysis has been completed to identify potential network design hazards that could cause an error or injury to the user or service personnel. Appropriate steps have been taken to control all identified risks for this type of network communications system.

**8) Conclusions:**

The MedLink Workstation Network is designed and manufactured to meet United States and international open communications standards to facilitate compatibility with diagnostic imaging systems, printers, and archival devices. The system is designed to incorporate components common to all image management systems for printing, review, archival, retrieval, and communications within a clinical setting or at remote locations. These components can be combined into customized solutions for the management of patient and image information along a networked pathway easily and efficiently. The MedLink Workstation incorporates features of predicate devices cleared through premarket notifications and no new issues of safety or effectiveness are raised by its incorporation of the DICOM standard to facilitate open network communications for the management of patient and imaging information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Re: K002144
MedLink Diagnostic Offline Workstation
Dated: July 14, 2000
Received: July 17, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Sweeney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002144

Device Name: MedLink Diagnostic Offline Workstation

Indications for use:

The MedLink Diagnostic Offline Workstation is an image management system that provides the capability for the acquisition, display, storage, retrieval, quantitative analysis, and reporting of medical images and patient data at a single or multiple locations.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002144